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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/636,072 | 08/06/2003 | James Lousararian | ANG 00.03 CIP5 | 9838 |
| 32047 | 7590 | 10/31/2006 | EXAMINER | |
| GROSSMAN, TUCKER, PERREAULT & PFLEGER, PLLC 55 SOUTH COMMERCIAL STREET MANCHESTER, NH 03101 | | | YABUT, DIANE D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3734 | |

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/636,072

Applicant(s)

LOUSARARIAN ET AL.

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 5-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>1/2/04; 2/17/04; 6/4/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS: 3/9/06; 5/23/06</u> . |

Art Unit: 3734

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, drawn to claims 1-17 and Species I, shown in Figures 72, 75, and 76 in the reply filed on 18 October 2006 is acknowledged.
2. Claims 18-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 October 2006.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 2 January 2004, 17 February 2004, 4 June 2004, 9 March 2006, and 23 May 2006 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

4. Claim 7 is objected to because of the following informalities: On lines 1-2 of the claim it reads "member is polymer sheet" and should rather read --member is a polymer sheet--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Paolitto et al., or **Paolitto** (U.S. Pub. No. **20030093091**).

Claims 1 and 7: Paolitto discloses a pledget **40** of polymeric sheet material comprising a member configured to be retained adjacent to a wound site by a staple, said member comprising a base region configured to be at least partially disposed between a plurality of prongs of a staple, said member further comprising a plurality of peripheral notches **403**, **404** configured to at least partially receive said plurality of prongs therein, said notches further being configured to engage said plurality of prongs to retain said member to said staple (Figures 7A-7C and pages 9-10, paragraph 115).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3734

8. Claims 5, 6, 8, 9, 11, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Paolitto** (U.S. Pub. No. **20030093091**) in view of **Hain** (U.S. Pub. No. **20040162580**).

Claims 5, 6, 8, 9-11, 14 and 17: Paolitto discloses the claimed device except for the member comprising a woven or non-woven fabric material comprising polyester material, the member being bioabsorbable, the member comprising a physiologically active agent, the physiologically active agent adapted to be released over a predetermined time interval, the physiologically active agent comprising a coating applied to said member, the physiologically active agent comprising an anti-microbial agent, and the physiologically active agent promoting extraluminal clotting.

Hain teaches a member comprising a woven or non-woven fabric material comprising polyester material, the member being bioabsorbable, the member comprising a physiologically active agent, the physiologically active agent adapted to be released over a predetermined time interval, the physiologically active agent comprising a coating applied to said member, the physiologically active agent comprising an anti-microbial agent ("silver oxide"), and the physiologically active agent promoting extraluminal clotting ("collagen") (page 2, paragraph 28, pages 9-10, paragraphs 88-95). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a woven or non-woven fabric material comprising polyester material, as taught by Hain, to the pledget of Paolitto since it was known in the art that woven, polyester material has absorbent properties. It would have been obvious to one of ordinary skill to provide a bioabsorbable pledget, as taught by Hain, to Paolitto since it was known in the

Art Unit: 3734

art that it removes the need to surgically remove the device. It would have been obvious to one of ordinary skill to provide a physiologically active agent adapted to be released over a predetermined time interval in order to provide controlled, sustained release provides therapeutic benefits that can last from minutes to weeks or longer. It would have been obvious to one of ordinary skill in the art to provide a physiologically active agent comprising a coating applied to said member, the physiologically active agent comprising an anti-microbial agent since it was known in the art that coatings contact tissue directly and anti-microbial agents minimize bacterial growth in, on or near the pledget.

9. Claims 12, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Paolitto** (U.S. Pub. No. **20030093091**) in view of **Hain** (U.S. Pub. No. **20040162580**) as applied to Claim 9 above, and further in view of **Marlar et al.**, or **Marlar** (U.S. Patent No. **5,093,263**).

Claims 12, 13 and 16: Paolitto and Hain disclose the claimed device except for said member being impregnated with said physiologically active agent and formed from said physiologically active agent which inhibits intraluminal clotting.

Marlar teaches a pledget member being impregnated with said physiologically active agent formed from said physiologically active agent which inhibits intraluminal clotting ("heparin") (col. 3, lines 21-33). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a member being impregnated with said physiologically active agent and formed from said physiologically active agent which

Art Unit: 3734

inhibits intraluminal clotting, as taught by Marlar, to Paolitto and Hain in order to effectively anticoagulate blood.

10. Claims 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Paolitto** (U.S. Pub. No. **20030093091**) in view of **Hain** (U.S. Pub. No. **20040162580**) as applied to Claim 9 above, and further in view of **Mandelbaum** (U.S. Patent No. **4,221,215**).

Claim 15: Paolitto and Hain disclose the claimed device except for said physiologically active agent comprising an antiseptic agent.

Mandelbaum teaches a physiologically active agent comprising an antiseptic agent (col. 5, lines 55-67). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a physiologically active agent comprising an antiseptic agent, as taught by Mandelbaum, to Paolitto and Hain since it was known in the art that antiseptic agents prevent the growth and reproduction of harmful bacteria and viruses.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER